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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/910,628	07/20/2001	Judith L. Erb	3060.00021	3205

7590 11/24/2003

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EXAMINER

CHIN, CHRISTOPHER L

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 11/24/2003

15

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/910,628

Applicant(s)
Erb et al

Examiner
Chris Chin

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1641



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Sep 17, 2003
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.
- ## Disposition of Claims
- 4) ☒ Claim(s) 43-49 is/are pending in the application.
- 4a) Of the above, claim(s) 46, 47, and 49 is/are withdrawn from consideration
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 43-45 and 48 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claims 43-49 are subject to restriction and/or election requirement

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

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DETAILED ACTION

Claim Rejections - 35 U.S.C. § 112

1. Claims 45 and 48 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 45 and 48 are vague because it is not clear as to how the tumor tissue is related to the components and/or reagents in the apparatus of claim 43. Claim 48 is further vague because it is an identical duplicate of claim 45.

Claim Rejections - 35 U.S.C. § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 43 and 44 are rejected under 35 U.S.C. 102(b) as being anticipated by Charles et al.

Charles et al (WO 90/11525) discloses a surface plasmon resonance (SPR) sensor (i.e. an evanescent sensing device) and method of immunoassay using the SPR sensor. The disclosed

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method is for assaying for an analyte which is a member of a specific binding pair, by the use of a solid surface carrying immobilized thereon a first reagent which is a member of the specific binding pair, and a second reagent which is a conjugate of a member of the specific binding pair, at least one of the first and second reagents being a specific binding partner of the analyte. The method comprises incubating a fluid sample containing the analyte with the first and second reagents simultaneously or in any desired order, whereby the conjugate is caused to be present on the solid surface in a manner related to the presence of the analyte in the sample. The solid surface is a metallic layer of the SPR sensor. The presence of the conjugate on the surface is assayed by SPR spectrometry and the conjugate is selected to be capable of giving a strong SPR signal. In one embodiment, competitive assays are disclosed where either (a) the first reagent is an analogue of the analyte and the second reagent is a conjugate of a specific binding partner of the analyte, or (b) the first reagent is a specific binding partner of the analyte and the second reagent is a conjugate of an analogue of the analyte (see pages 2-3). In another embodiment, a sandwich assay is disclosed where both the first and second reagents are specific binding partners of the analyte (see page 6). The conjugate carries a label reagent that gives a strong SPR signal. The label can be metal particles or an enzyme (see page 5).

The "molecular tag" recited in the instant apparatus is analogous to the conjugate in Charles et al. In the assays of Charles et al, the conjugate is either displaced (in the competitive assay) by analyte binding or bound to the analyte (in the sandwich assay) when analyte is bound

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to the immobilized first reagent and thus produces an alteration in SPR signal in response to the presence of analyte.


Conclusion

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chris Chin whose telephone number is (703) 308-3991. The examiner can normally be reached on Monday-Thursday from 10:00 am to 7:30 pm. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, can be reached on (703) 305-3399.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

cchin/cc
November 22, 2003


CHRISTOPHER L. CHIN
PRIMARY EXAMINER
GROUP 1800-1641